NDA
505(b)(1) of the FD&C Act

- **Application used for approval of a new drug (for clinical use) whose active ingredient has not previously been approved**
- **Requires extensive data to establish:**
  - **Safety and effectiveness of the drug for the proposed uses**
  - **Production methods are adequate to ensure identity, strength, quality, purity of the drug**
  - **Proposed labeling is appropriate and contains all necessary information**

NDA
505(b)(2) of the FD&C Act

- **Application for approval of a new drug that relies, at least in part, on data not developed by the applicant**
- **Must provide information to establish:**
  - **Safety and effectiveness of the drug for its proposed uses**
    - **Not necessarily full reports of studies—may rely on published literature, findings of safety and effectiveness for already approved products, studies conducted by others with no right of reference, and/or FDA's PET Safety and Effectiveness Notice**
  - **Production methods are adequate to ensure identity, strength, quality, purity of the drug**
  - **Proposed labeling for the drug is appropriate and contains all necessary information**

ANDA
505(j) of the FD&C Act

- **Application used for approval of a "generic" version of a drug that has already been approved**
- **Relies on FDA's finding that the previously approved reference listed drug (RLD) is safe and effective**
- **Must provide information to establish that the proposed generic is the same as the RLD in:**
  - **Active ingredient**
  - **Strength**
  - **Dosage form**
  - **Route of administration**
  - **Conditions of use**
- **Must demonstrate that the proposed generic is bioequivalent to the RLD**

Investigational New Drug (IND)

- INDs are generally for drugs that are still in the investigational stage of development and not ready (or not appropriate) for an NDA
- With an IND, a drug can be administered to humans as part of a clinical trial to assess the safety and effectiveness of the drug
- Expanded access INDs can be used to provide patients with access to investigational drugs outside of a clinical trial
  - This may be useful for PET drugs that are used too rarely to justify the submission of an NDA
- Drugs may not be marketed for commercial clinical use under an IND
- Sponsors can get permission to charge for an investigational drug to recoup costs of producing the drug

Radioactive Drug Research Committee (RDRC)

- **Permits use of radiopharmaceuticals in humans without an NDA, ANDA, or IND**
- **Limitations on RDRC research include:**
  - **Must be basic science research (e.g., regarding drug metabolism, human physiology, biochemistry)**
  - **Not intended to evaluate safety or efficacy of the drug**
  - **Not intended for immediate therapeutic or diagnostic purposes**
  - **Dose must be within specified limits**
  - **Dose not known to cause any clinically detectable pharmacologic effect**